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09/284,180	06/09/99	KIMURA T	20-4546P

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EXAMINER	
CHEN, S	
ART UNIT	PAPER NUMBER
1633	21

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/284,180	KIMURA ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-55* is/are pending in the application.

4a) Of the above claim(s) *53-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Applicants' amendment filed 3-28-01 and declaration filed 4-21-01 have been entered. Claims 1-14 and 16-33 have been canceled. Claims 34-55 have been added. Claims 34-55 are pending. Claims 34-52 are under consideration.

It should be noted that claims 53-55 are drawn to non-elected invention according to the Official action mailed 8-9-00 (Paper No. 13). Therefore, claims 53-55 are withdrawn from consideration by examiner.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 34-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants amendment filed 3-28-01 necessitates this new ground of rejection.

The claims read on an isolated nucleic acid **comprising** a polynucleotide having the nucleotide sequence of SEQ ID No. 4, 1-1761 of SEQ ID No. 4, or SEQ ID No. 10, or a nucleotide sequence encoding SEQ ID No. 6 or 11; an isolated nucleic acid comprising a

polynucleotide that encodes a protein comprising a semaphorin domain and hybridizes with 76-2406 of SEQ ID No. 1 or SEQ ID No. 7 under the condition specifies in the claims; an isolated nucleic acid comprising a polynucleotide having a nucleotide sequence that is at least 80% or 90% identical to the nucleotide sequence of SEQ ID No. 1, 76-2406 of SEQ ID No. 1, or 259-1776 of SEQ ID No. 1, or a nucleotide sequence encoding SEQ ID No. 3 or 62-567 of SEQ ID No. 3, and that encodes a protein comprising a semaphorin domain, or a protein having the biological activity of inhibiting neurite outgrowth from dorsal root ganglion or collapsing growth cones of retinal ganglion cells; an isolated nucleic acid comprising a polynucleotide that hybridizes with the nucleotide sequence of SEQ ID No. 1, 76-2406 of SEQ ID No. 1, SEQ ID No. 4, 1-1761 of SEQ ID No. 4, or SEQ ID No. 10, and that encodes a protein having the biological activity of inhibiting neurite outgrowth from dorsal root ganglion or collapsing growth cones of retinal ganglion cells; and an isolated nucleic acid comprising a polynucleotide having the sequence of 27 or more contiguous nucleotides of SEQ ID No. 1, 4, or 10.

The claims encompass various nucleic acids having unknown nucleotide sequence adding to 5' and/or 3' end of SEQ ID No. 4, 10, or a nucleotide sequence encoding SEQ ID No. 6 or 11, nucleic acids comprising polynucleotides having unknown nucleotide sequences adding to 5', 3' and/or within the sequence of SEQ ID No. 1, 76-2406 of SEQ ID No. 1, 259-1776 of SEQ ID No. 1, SEQ ID No. 4, 1-1761 of SEQ ID No. 4, SEQ ID No. 10, or a nucleotide sequence encoding SEQ ID No. 3 or 62-567 of SEQ ID No. 3, and an isolated nucleic acid comprising a polynucleotide having the sequence of 27 or more contiguous nucleotides of SEQ ID No. 1, 4, or

10. The specification of the present application only disclosed the nucleotide sequences of SEQ ID Nos. 1 and 2 (rat semaphorin) and the amino acid sequence deduced from SEQ ID No. 2 (SEQ ID No. 3), and the nucleotide sequences of human semaphorin cDNA (SEQ ID Nos. 4, 5, 7 and 10).

The scope of the claim includes various unknown and unidentified nucleic acids encoding a genus of numerous structural variants of the disclosed semaphorin protein (SEQ ID No. 3), and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification only discloses the homologies of the primary amino acid sequences in semaphorin domain among the known semaphorin genes are 20-80% and not necessarily high (specification, page 4, lines 17-20), and suggest that the amino acid residue at position 204 of SEQ ID No. 3 could be essential to the activity of semaphorin protein (specification, page 18, lines 17-22). The specification indicates the ""semaphorin domain" refers to a domain consisting of 300-600 amino acid residues more than 20% of which are identical to those amino acids constituting the semaphorin domain of any one of ten known semaphorins" and thirteen cysteines are conserved in semaphorin domain of the ten known semaphorins (Specification, page 23, lines 10-13 and 22-24). The amino acid sequences between semaphorin domains of the known semaphorins could differ from 240-480 amino acid residues which account to 720-1440 nucleotide difference among the known semaphorin domains. The identical amino acid residues among semaphorin domains of the known semaphorin are not necessarily identical throughout all known semaphorin rather they are identical to a certain

subgroups of the known semaphorins. The claimed nucleic acids could vary dramatically from the disclosed nucleotide sequences of the present application. No common structural feature of the nucleic acids that encode the semaphorin domain has been disclosed in the specification except the consensus cysteine residues. Thus, one skilled in the art at the time of the invention would not know how to distinguish the nucleic acid encoding semaphorin protein from the nucleic acid encoding other proteins.

The specification fails to provide any domain or region within a semaphorin that contributes to any functional characteristic of the semaphorin other than the proposed position 204 of SEQ ID No. 3 and no specific guidance has been provided for any addition, deletion or substitution that would still retain the function of the semaphorin W protein as disclosed in the present application. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus other than the semaphorin domain discussed above. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of SEQ ID No. 3 is insufficient to describe the genus. This limited information is not sufficient to reasonably convey to one skilled in the art that applicants were in possession of all the nucleic acids encoding variants of the semaphorin W disclosed in the

present invention. Thus it is concluded that the written description requirement is not satisfied for the nucleic acids that encode the genus of proteins discussed above.

Further, the nucleotide sequences of SEQ ID No. 4, 7 and 10 are only partial cDNA sequence, no full length open reading frame (ORF) is disclosed. An isolated nucleic acid, **comprising** a polynucleotide having the nucleotide sequence of SEQ ID No. 4, 1-1761 of SEQ ID No. 4, or SEQ ID No. 10, or a nucleotide sequence encoding SEQ ID No. 6 or 11, encompasses a variety of subgenera with widely varying attributes. A partial cDNA that did not include a disclosure of any ORF of which it would be a part, would not be representative of the genus of cDNAs because no information regarding the coding capacity of any cDNA molecule would be disclosed. Further, defining the cDNA in functional terms would not suffice in the absence of a disclosure of structural features or elements of a cDNA that would encode a protein having a stated function. The specification discloses only a single common structural feature shared by the member of the claimed genus, i.e. SEQ ID No. 4, 7, or 10. Since the claimed genus encompasses genes yet to be discovered, DNA constructs that encode fusion proteins, etc., the disclosed structural feature does not constitute a substantial portion of the claimed genus. Therefore, the disclosure of SEQ ID No. 4, 7, or 10 does not provide an adequate description of the claimed genus.

Weighing all factors, 1) partial structure of the nucleic acids that comprises SEQ ID No. 4, 7, or 10, 2) the breadth of the claims as reading on genes yet to be discovered in addition to numerous fusion constructs and cDNAs, 3) the lack of correlation between the structure and the

function of the genes and/or fusion constructs; in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of nucleic acids which comprises SEQ ID No. 4, 10, or a nucleotide sequence encoding SEQ ID No. 6 or 11.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieved regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to

lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the disclosed SEQ ID Nos. 1, 2, 4, 5, 7 and 10, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Applicants argue that "semaphorin domain" in new claims is well-known in the art as a characteristic structure of semaphorins and one skilled in the art can envisage the detailed chemical structure of a semaphorin domain and determine whether an isolated polynucleotide encodes all or part of a semaphorin domain. Applicants further argue that semaphorin domain accounts for a considerable portion in the proteins having semaphorin activity (Exhibit 2) and the presence of a semaphorin domain would establish a reasonable expectation of semaphorin activity (amendment, page 13, 14). This is not found persuasive because of the reasons set forth above in the 112 first written description section and that the region outside the semaphorin domain also would contribute to the biological function of a semaphorin protein since the semaphorin domain only accounts for about 1/3 to 2/3 of the biological function of a semaphorin protein. The nucleotide sequence encoding the region outside the semaphorin domain has not been sufficiently described by the specification of the present application.

Applicants argue that "adequate written description of a claimed invention can be provided by either a structural or a functional feature that defines the genus of molecules encompassed by the claims" (amendment, page 15). This is not found persuasive because of the reasons set forth above in the 112 first written description section.

3. Claims 34-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA comprising SEQ ID No. 1 or 2 and a DNA encoding a polypeptide sequence of SEQ ID No. 3 that functions to inhibit neurite outgrowth, does not reasonably provide enablement for any isolated nucleic acid comprising SEQ ID No. 4, 1-1761 of SEQ ID No. 4, or SEQ ID No. 10, or a nucleotide sequence encoding SEQ ID No. 6, or 11; an isolated nucleic acid comprising a polynucleotide that encodes a protein comprising a semaphorin domain and hybridizes with 76-2406 of SEQ ID No. 1 or SEQ ID No. 7 under the condition specifies in the claims; an isolated nucleic acid comprising a polynucleotide having a nucleotide sequence that is at least 80% or 90% identical to SEQ ID No. 1, 76-2406 of SEQ ID No. 1, or 259-1776 of SEQ ID No. 1, or a nucleotide sequence encoding SEQ ID No. 3 or 62-567 of SEQ ID No. 3; an isolated nucleic acid comprising a polynucleotide that hybridizes with the nucleotide sequence of SEQ ID No. 1, 76-2406 of SEQ ID No. 1, SEQ ID No. 4, 1-1761 of SEQ ID No. 4, or SEQ ID No. 10, and that encodes a protein having the biological activity of inhibiting neurite outgrowth from dorsal root ganglion or collapsing growth cones of retinal ganglion cells; and an isolated nucleic acid comprising a polynucleotide having the sequence of

27 or more contiguous nucleotides of SEQ ID No. 1, 4, or 10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants amendment filed 3-28-01 necessitates this new ground of rejection.

The claims are drawn to an isolated nucleic acid comprising a polynucleotide having the nucleotide sequence of SEQ ID No. 1, SEQ ID No. 4, 1-1761 of SEQ ID No. 4, or SEQ ID No. 10, or a nucleotide sequence encoding SEQ ID No. 3, 6, or 11; an isolated nucleic acid comprising a polynucleotide that encodes a protein comprising a semaphorin domain and hybridizes with 76-2406 of SEQ ID No. 1 or SEQ ID No. 7 under the condition specifies in the claims; an isolated nucleic acid comprising a polynucleotide having a nucleotide sequence that is at least 80% or 90% identical to the nucleotide sequence of SEQ ID No. 1, 76-2406 of SEQ ID No. 1, or 259-1776 of SEQ ID No. 1, or a nucleotide sequence encoding SEQ ID No. 3 or 62-567 of SEQ ID No. 3, and that encodes a protein comprising a semaphorin domain, or a protein having the biological activity of inhibiting neurite outgrowth from dorsal root ganglion or collapsing growth cones of retinal ganglion cells; an isolated nucleic acid comprising a polynucleotide that hybridizes with the nucleotide sequence of SEQ ID No. 1, 76-2406 of SEQ ID No. 1, SEQ ID No. 4, 1-1761 of SEQ ID No. 4, or SEQ ID No. 10, and that encodes a protein having the biological activity of inhibiting neurite outgrowth from dorsal root ganglion or collapsing growth cones of retinal ganglion cells; and an isolated nucleic acid comprising a

polynucleotide having the sequence of 27 or more contiguous nucleotides of SEQ ID No. 1, 4, or 10.

The claims encompass various nucleic acids having unknown nucleotide sequence adding to 5' and/or 3' end of SEQ ID No. 4, 10, or a nucleotide sequence encoding SEQ ID No. 6 or 11, nucleic acids comprising polynucleotides having unknown nucleotide sequences adding to 5', 3' and/or within the sequence of SEQ ID No. 1, 76-2406 of SEQ ID No. 1, 259-1776 of SEQ ID No. 1, SEQ ID No. 4, 1-1761 of SEQ ID No. 4, SEQ ID No. 10, or a nucleotide sequence encoding SEQ ID No. 3 or 62-567 of SEQ ID No. 3, and an isolated nucleic acid comprising a polynucleotide having the sequence of 27 or more contiguous nucleotides of SEQ ID No. 1, 4, or 10. The specification of the present application only disclosed the nucleotide sequences of SEQ ID Nos. 1 and 2 (rat semaphorin W) and the amino acid sequence deduced from SEQ ID No. 2 (SEQ ID No. 3), the nucleotide sequences of human semaphorin cDNA (SEQ ID Nos. 4, 5, 7 and 10), and the function of said rat semaphorin W protein.

The scope of the claim includes various unknown and unidentified nucleic acids encoding a genus of numerous structural variants, derived from different organisms including humans, cows, dogs, mice, whales, fish, insects, plants etc., of the disclosed semaphorin protein (SEQ ID No. 3), and the genus is highly variant because a significant number of structural differences between genus members is permitted.

The specification fails to provide adequate guidance for a domain or a region within a semaphorin that contributes to any functional characteristic of the semaphorin having the

sequence of SEQ ID No. 3 other than the proposed amino acid residue at position 204 of SEQ ID No. 3 and somaphorin domain. There is no indication of regions or specific amino acids within the semaphorin where mutations or variations would be tolerated without any change of the functional characteristic of the semaphorin and regions where they would not be tolerated other than the proposed amino acid residue at position 204 of SEQ ID No. 3. The amino acid sequence of a protein determines its structural and functional properties, and predictability of which amino acids can be removed from a protein's sequence and still result in similar activity is extremely complex, and well outside the realm of routine experimentation, because accurate predictions of a protein's structure from mere sequence data are limited. Rudinger, 1976 (W) points out that "The significance of particular amino acids and sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study" (e.g. p. 6). Therefore, one skilled in the art at the time of the invention would not be able to predict the function of a protein merely from the amino acid sequence of said protein.

As discussed above, "semaphorin domain" refers to a domain consisting of 300-600 amino acid residues more than 20% of which are identical to those amino acids constituting the semaphorin domain of any one of ten known semaphorins" (Specification, page 23, lines 10-13). The amino acid sequences between semaphorin domains of the known semaphorins could differ from 240-480 amino acid residues which could dramatically affect the function of a protein. In addition, the amino acid sequence outside the semaphorin domain of the semaphorin protein

could also influence the biological function of a protein as a whole. In view of such, unpredictability of the biological function of a protein, and the lack of detailed information regarding the structural and functional requirements of a semaphorin, it would be unpredictable whether the claimed nucleic acids would still retain the functional characteristic of the amino acid sequence of SEQ ID No. 3.

Further, the nucleotide sequences of SEQ ID Nos. 4, 5, 7 and 10 are partial cDNA sequence of human semaphorin. The specification of the present application fails to provide the full-length open reading frame (ORF) of the human semaphorin and fails to provide adequate guidance and evidence for the function of the protein encoded by said full length ORF of human semaphorin. It is unclear whether a human semaphorin would have the same function as the rat semaphorin W disclosed in the present application.

Therefore, it is concluded that based upon the nature of the claimed invention, the state of the art, the unpredictability found in the art, the teaching and working examples provided, and the breadth of the claims that one skilled in the art at the time of the invention would have had to engage in undue experimentation to practice over the full scope of the invention claimed.

The quantity of the experimentation required to practice the invention claimed would include: isolation, purification and characterization of various semaphorin variants of SEQ ID No. 3, determination of the function of said semaphorin variants, determining the structural features and functional domains within the semaphorin that contributes to its function of

inhibiting neurite outgrowth, trial and error experimentation to determine what mutations or variations of SEQ ID No. 3 would still retain the functional characteristic of the semaphorin W.

It should be noted that unpredictability of biological function of a protein alone could render one skilled in the art at the time of the invention undue experimentation to practice over the full scope of the invention claimed.

Applicants argue that In re wands factors are required for determining enablement of a claimed invention (amendment, page 16-19). Applicants further provide declaration of Dr. Kimura that shows the isolation and characterization of a nucleic acid molecule comprising a semaphorin domain or having the activity of a semaphorin protein as claimed (amendment, page 19). This is not found persuasive because of the reasons set forth above in the 112 first enablement section and that the teaching of prior arts is not sufficient for one skilled in the art to predict the biological function of a semaphorin protein. Sufficient structural features that contribute to the biological function of a semaphorin protein are still lacking. Although the method of isolating and characterizing a nucleic acid that might comprise a semaphorin domain and have the activity of a semaphorin protein are known in the art, one skilled in the art would still require undue experimentation to practice over the full scope of the invention claimed because of the unpredictability of the biological function of a protein and the lack of detailed information of the structural features that contribute to the activity of a semaphorin protein.

Applicants argue that Exhibit 4 shows the nucleic acid sequences of SEQ ID Nos. 4 and 10 constitute parts of the human homolog of rat semaphorin cDNA (amendment, page 20). This is not found persuasive because SEQ ID Nos. 4, 7, and 10 only disclose partial cDNA sequence of human semaphorin W at the time of the invention. The disclosed human sema W transcript in Exhibit 4 encodes a protein having 608 amino acids which is different from the 587 amino acids encoded by SEQ ID No. 4. It is unclear how the human sema W protein disclosed in Exhibit 4 correlate to the amino acid sequences encoded by SEQ ID Nos. 4, 7, and 10. Further, the article of Exhibit 4 was published in 1999 that is about 3 years later than the effective filing date of the present application, i.e. 10-9-96. Thus, applicants has not enabled a nucleic acid comprising a polynucleotide having the nucleotide sequence of SEQ ID No. 4, 7, or 10.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 51 and 52 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hillier et al., EST Accession No. H24181, July 1995. Applicants amendment filed 3-28-01 necessitates this new ground of rejection.

Claims 51 and 52 are directed to an isolated nucleic acid molecule comprising a polynucleotide having 27 or more contiguous nucleotides of SEQ ID No. 1, 4, or 10 or an isolated nucleic acid molecule that is complementary to said nucleic acid with the exception of GenBank Accession No. T09073 and R54387.

Hillier teaches a human cDNA clone, EST Accession No. H24181, that is 100% identical to base 488 to 785 of SEQ ID No. 4, and said cDNA clone has at least 27 contiguous nucleotides and it is inherent to have a nucleotide sequence that is complementary to said cDNA clone. Thus, claims 51 and 52 are clearly anticipated by Hillier.

6. Claims 51 and 52 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Igarashi et al., N_Geneseq_0401 Accession No. Q56609, 1994. Applicants amendment filed 3-28-01 necessitates this new ground of rejection.

Claims 51 and 52 are directed to an isolated nucleic acid molecule comprising a polynucleotide having 27 or more contiguous nucleotides of SEQ ID No. 1, 4, or 10 or an isolated nucleic acid molecule that is complementary to said nucleic acid with the exception of GenBank Accession No. T09073 and R54387.

Igarashi teaches a human nucleic acid, N_Geneseq_0401 Accession No. Q56609, that is 100% identical to base 3355 to 3402 of SEQ ID No. 1, and said nucleic acid has at least 27 contiguous nucleotides and it is inherent to have a nucleotide sequence that is complementary to said nucleic acid. Thus, claims 51 and 52 are clearly anticipated by Igarashi.

Conclusion

No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See M.E.P.. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Kimberly Davis, whose telephone number is (703) 305-3015.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

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